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Dated: September 30, 2003

Signature:

Richard Zimmermann

Docket No.: 29915/00281A  
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Yan *et al.*

Application No.: 09/908,943

Group Art Unit: 1652

Filed: July 19, 2001

Examiner: Charles L. Patterson, Jr.

For: SUBSTRATES AND ASSAYS FOR  
 $\beta$ -SECRETASE ACTIVITY

**PETITION TO WITHDRAW FINALITY OF OFFICE ACTION AS PREMATURE  
PURSUANT TO 37 C.F.R. §1.181**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.181, the Applicants petition the Commissioner to vacate the finality of the Office action dated July 31, 2003 received in the above-identified case, and to redesignate the Office action as a **non-final** action.

**I. Statement of Facts**

1. The application as filed included original claims 1-82, attached as Exhibit A.
2. In response to a 442-way restriction requirement (Exhibit B, which will be the subject of a separate petition), the Applicants elected Group 56, which included Claims 21-27, drawn to a peptide, which in addition to other features comprises a generic sequence defined as  $P_2P_1\text{--}P_1'P_2'$  in which  $P_1$  is Y.
3. Applicants' election in response to the restriction requirement was made *with traverse*.

4. In the first Office action (Exhibit C), dated February 21, 2003, the maintained the restriction requirement and withdrew claims that were directed to any subject matter in which P<sub>1</sub> was not Y. (See Exhibit C, page 3.)

5. On May 21, 2003, Applicants filed a response to the Office action referenced in paragraph 3. In that response, the Applicants amended independent claims 21 and 27 to conform to their election, because, as originally filed, P<sub>1</sub> was defined in these claims as "P<sub>1</sub> comprises an amino acid selected from the group consisting of is Y, L, and Nle." However, as the election in response to the restriction requirement was to elect P<sub>1</sub> as Y, Applicants amended these claims to remove the term of "L, and Nle." A further clause in the claim which pertained to embodiments where P<sub>1</sub> was "L" was deleted as irrelevant. Applicants further presented new claims 83 to 101, each of which either independently or dependently contained the feature which defined P<sub>1</sub> as Y.

6. The Office action referenced in paragraph 3, did articulate prior art rejections of claims 21-27. However, the Applicants traversed those rejections and distinguished that art by argument, and not by way of amendment. More particularly, claims 21-27 were rejected under 35 U.S.C. §102(b) as allegedly anticipated or alternatively, under 35 U.S.C. §103(a) as obvious over any one of Sermjian *et al.* (*J. Mol. Biol.* 207:1-13, 1989), Van Camp *et al.*, (*Proc. Nat'l. Acad. Sci.*, 87:9903-9907, 1990), Lowell *et al.*, (*J. Biol. Chem.*, 261(18):8442-8452, 1986) or Sellar *et al.*, (*J. Biol. Chem.*, 266(6):3505-3510, 1991) (All attached as Exhibit D). The documents failed to defeat the novelty of, or render obvious, the subject matter of the claims because these references failed to provide any teaching of an isolated peptide "of between about 4 amino acids and about 50 amino acids in length." This limitation was an express feature of claims 21-27 *as originally filed*.

7. The prior art rejections discussed in paragraph 5 were not repeated with respect to claims 21-27, and Applicants therefore submit that the arguments presented in response to those arguments overcame the prior art rejections of claims 21-27 articulated in the Office action of February 21, 2003. The Examiner, however, articulated a rejection of new claims 83 and 85 over the art of record.

8. On August 31, 2003, the Office mailed a second, final Office action (Exhibit D), in which the Examiner entered a new prior art rejection under 35 U.S.C. §102(b) based on Sano *et al.*, (U.S. Patent No. 5,637,490), applying the reference to claims 21, 23, 25-27, 83-85 and 89. In the Office action, the Examiner stated that the Sano *et al.* document "teaches in SEQ ID NO:4 the sequence Asp-Tyr-Asp-Ala in residues 10-13. *The peptide is 20 amino acids in length.*" (Emphasis added).

9. The Sano *et al.* reference was uncovered by the Examiner, and was not identified in an IDS submission under 37 C.F.R. 1.97(c).

## II. Legal Authority upon Which Instant Petition is based

According to the Patent Office guidelines set forth in the MPEP, "[u]nder present practice, second or any subsequent actions on the merits shall be final, *except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).*" MPEP 706.07(a) (emphasis added).

The MPEP further provides that, "[a] second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection, on prior art not of record, of any claim *amended to include limitations which should reasonably have been expected to be claimed.* See MPEP § 904 et seq. For example, one would reasonably expect that a rejection under 35 U.S.C. 112 for the reason of incompleteness would be replied to by an amendment supplying the omitted element." *Id.* (Emphasis added.)

## III. Reasons that Requested Petition Should be Granted

The MPEP does not allow a second action to be deemed final where the Examiner introduces a new ground of rejection that was neither necessitated by the

Applicant's amendment, nor based on information submitted by the Applicant. *See* MPEP 706.07(a). The final Office action dated August 31, 2003 rejected the claims under 35 U.S.C. §102(b) based on a new reference, Sano *et al.*, because this document discloses SEQ ID NO:4, which is a peptide of 20 amino acids in length. (see fact paragraph 7). The rejection based on Sano *et al.* in the final Office action was in no way based upon the amendments to claims 21 and 27 which were made to conform the claims to the election made in response to the restriction requirement (see fact paragraph 4). In fact, as claims 21-27 each included the limitation that the peptides be "of between about 4 amino acids and about 50 amino acids in length," there is no reason why the rejection of those claims over the Sano *et al.*, reference could not have been made to the claims prior to Applicants' filing of the May 21, 2003 response to the Office action dated February 21, 2003 (see fact paragraphs 3 & 4).

Furthermore, the Sano *et al.* document was not submitted by the Applicants. Sand was identified by the Examiner in the most recent Official Action (see fact paragraph 8).

Moreover, the MPEP mandates that, even when amendments have been made, a second action should not be made final if it includes a rejection, on prior art not of record, of any claim ***amended to include limitations which should reasonably have been expected to be claimed***. In the present case, the amendments to the claims were made in order to conform the claims to the elected group pursuant to a restriction requirement (see fact paragraph 4). In view of the Examiner making the restriction requirement final and withdrawing consideration of all claims in which P<sub>1</sub> is not Y, the Examiner should reasonably have expected the Applicants to make the amendments that were made in response to the first action on the merits. Thus, even if the Commissioner were to conclude that the new rejection was necessitated by the Applicants' amendments, the second action still should not be final, because the amendments were made at the Examiner's direction, and should therefore, reasonably have been expected.

As (1) Examiner's rejection based on Sano *et al.* would have been equally applicable to the original claims as to the claims that Applicants presented in the May 21,

2003 response; (2) the Sano *et al.* reference was cited and applied by the Examiner for the first time in the most recent "final" Office action; and (3) the Examiner should reasonably have expected the amendments that were made to claims 21 and 27 in view of his stance on the restriction requirement, the finality is improper. Therefore, pursuant to MPEP §706.07(a) the finality of the Office action dated August 31, 2003 must be withdrawn.

#### IV. Conclusions

Applicants believe that the Office action dated August 31, 2003 was inappropriately designated a final Office action for the reasons detailed above, and therefore Applicants request that the petition be granted. No fee is believed to be due with the filing of a petition pursuant to 37 C.F.R. §1.181, however, should a fee be deemed necessary in connection with the filing of this petition the Commissioner is hereby authorized to deduct such a fee from Marshall, Gerstein and Borun account number 13-2855.

Dated: September 30, 2003

Respectfully submitted,

By   
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